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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/558,149	04/26/2000	Nicholas Nicolaides	01107.00004	1171

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Banner & Witcoff Ltd
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EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/558,149

Applicant(s)

NICOLAIDES ET AL.

Examiner

Ram R. Shukla

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13,14,18-20,29,52,53 and 58-62 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 13,14,18-20,29,52,53 and 58-62 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9-26-02 has been entered.

2. Claims 13, 14, 18-20, 29, 52, 53, and 58-62 are pending.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 13, 14, 18-20, 29, 52, 53, and 58-62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record set forth in the previous office action of 7-5-01 and 3-26-02.

5. Claims 13, 14, 18-20, 29, 52, 53, and 58-62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

possession of the claimed invention, for reasons of record set forth in the previous office action of 7-5-01 and 3-26-02.

Response to Arguments

Applicant's arguments filed 9-26-02 have been fully considered but they are not persuasive. In response to the enablement rejection applicants have cited Hybridtech Inc. v Monoclonal Antibodies Inc. and have argued that different sections of the specification (page 9, lines 21-28, page 9, lines 29- page 10, line 5) teaches the how to make the animal and that other methods of making a transgenic animal are known in the art. Applicants, in addition, have provided a declaration by Dr. Kline that a transgenic animal according to the invention could be made by following the teachings of the specification. It is noted that the declaration only indicates that a transgenic mouse was made and therefore, there is no evidence that any transgenic animal (non-human) could be made. Furthermore, while the declaration of Dr. Kline shows that a transgenic animal could be made, there is no direction or evidence in the declaration as to how would an artisan of skill have used the transgenic mouse made by Dr. Kline. The declaration only teaches that a transgenic mouse with PMS-134 deletion mutant was made which comprised the gene in its genome and expressed RNA (as evidenced by RT) in its organs, however, this does not address any of the issues raised in the previous rejection as to how would an artisan use the transgenic mouse, what were its characteristics or phenotypes etc. Additionally, the declaration does not address the issues of unpredictability of making any transgenic non-human mammal in view of the unpredictability of the method of transgenic animal production. In response to the issues raised in the previous office action of 3-26-02 (page 5), applicants have stated that mutations affect particular endogenous genes of interest of interest in animals that harbor a dominant negative allele of a mismatch repair gene, however, there is no evidence as to which endogenous genes are affected and therefore, without the genes known, how would an artisan know how to use the transgenic mouse. Next, applicants argue the utility of the transgenic animal.

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However, the issue is not the utility of the transgenic animal, rather, how to use it. Next, applicants argue that even in the presence of the wild type allele, the mismatch repair gene will work, still, there is no evidence as to what will happen in a transgenic animal due to this and what will be the consequence of this on the transgenic animal and how will an artisan use the transgenic animal.

Applicants' arguments that none of the claims recite wild type mismatch repair gene is persuasive.

Next, applicants argued that the effect of the dominant negative allele on metabolism or phenotype is that the cells in the animal to accumulate mutations at an abnormality high rate and correlate that human family with the mutation have tumors in children. However, these arguments are not persuasive because in view of the unpredictability of making transgenic animals, one could not predict what will be the effect or phenotype in a transgenic animal and the declaration by Dr. Kline does not indicate whether there was any tumor formation in the animal. It is noted that a transgenic animal is different from a human and therefore, the presence of a tumor in a human cannot be predicative of the effect in a transgenic animal.

In response to the written description rejection, applicants argue that the specification discloses on page 7, lines 1-12, 28-31 the transgenic animal and that the dominant negative allele produces a phenotype whereby mismatch repair is disrupted. However, page 7 of the specification nowhere discusses a transgenic animal. This section of the specification only talks about genes. The only reference to an animal is in line 28, however, there also there is no description of a transgenic animal. Regarding, the declaration by Dr. Kline, it is noted that while the shows constructive possession, it does not describe the characteristics of the transgenic animal and therefore, the description requirements of the transgenic animal are not met.

Double Patenting

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..."

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(Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claims 29, 52, 53 and 58-61 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 13-18 and 45-50 of co-pending Application No. 09/853,645. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

It is noted that the claimed invention in both the application are drawn to transgenic animals or transgenic mammals that comprise a dominant negative allele of mismatch repair gene, PMS2.

8. No claim is allowed.

When amending claims, applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to § 1.121(c). For instructions, Applicants are referred to <http://www.uspto.gov/web/offices/dcom/olia/aipa/index.htm>.

Applicants are also requested to submit a copy of all the pending/under consideration claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this


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application or proceeding should be directed to the Tiffiany N. Tabb whose telephone number is (703) 605-1238.

Ram R. Shukla, Ph.D.



RAM R. SHUKLA, PH.D
PATENT EXAMINER